

who has a financial relationship with an entity, or who has an immediate family member who has a financial relationship with the entity, may not make a referral to that entity for the furnishing of clinical laboratory services for which payment otherwise may be made under Medicare.

(b) *Limitations on billing.* An entity that furnishes clinical laboratory services under a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the clinical laboratory services performed under that referral.

(c) *Denial of payment.* No Medicare payment may be made for a clinical laboratory service that is furnished under a prohibited referral.

(d) *Refunds.* An entity that collects payment for a laboratory service that was performed under a prohibited referral must refund all collected amounts on a timely basis.

§ 411.355 General exceptions to referral prohibitions related to both ownership/investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) *Physicians' services.* as defined in § 410.20(a), that are furnished personally by (or under the personal supervision of) another physician in the same group practice as the referring physician.

(b) *In-office ancillary services.* Services that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.
(ii) A physician who is a member of the same group practice as the referring physician.

(iii) Individuals who are directly supervised by the referring physician or, in the case of group practices, by another physician in the same group practice as the referring physician.

(2) They are furnished in one of the following locations:

(i) A building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unre-

lated to the furnishing of clinical laboratory services.

(ii) A building that is used by the group practice for the provision of some or all of the group's clinical laboratory services.

(3) They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member.

(iii) An entity that is wholly owned by the physician or the physician's group practice.

(c) *Services furnished to prepaid health plan enrollees by one of the following organizations:*

(1) An HMO or a CMP in accordance with a contract with HCFA under section 1876 of the Act and part 417, subparts J through M, of this chapter.

(2) A health care prepayment plan in accordance with an agreement with HCFA under section 1833(a)(1)(A) of the Act and part 417, subpart U, of this chapter.

(3) An organization that is receiving payments on a prepaid basis for the enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 note).

(4) A qualified health maintenance organization (within the meaning of section 1310(d) of the Public Health Service Act).

(d) *Services furnished in an ambulatory surgical center (ASC) or end stage renal disease (ESRD) facility, or by a hospice* if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

§ 411.356 Exceptions to referral prohibitions related to ownership or investment interests.

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that may be

purchased on terms generally available to the public and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or

(ii) Traded under an automated inter-dealer quotation system operated by the National Association of Securities Dealers.

(2) In a corporation that had—

(i) Until January 1, 1995, total assets at the end of the corporation's most recent fiscal year exceeding \$100 million; or

(ii) Stockholder equity exceeding \$75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities:

(1) A laboratory that is located in a rural area (that is, a laboratory that is not located in an urban area as defined in § 412.62(f)(1)(ii) of this chapter) and that meets the following criteria:

(i) The laboratory testing that is referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the rural laboratory is either—

(A) Performed on the premises of the rural laboratory; or

(B) If not performed on the premises, the laboratory performing the testing bills the Medicare program directly for the testing.

(ii) Substantially all of the laboratory tests furnished by the entity are furnished to individuals who reside in a rural area. Substantially all means no less than 75 percent.

(2) A hospital that is located in Puerto Rico.

(3) A hospital that is located outside of Puerto Rico if one of the following conditions is met:

(i) The referring physician is authorized to perform services at the hospital, and the physician's ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.

(ii) Until January 1, 1995, the referring physician's ownership or investment interest does not relate (directly or indirectly) to the furnishing of clinical laboratory services.

§ 411.357 Exceptions to referral prohibitions related to compensation arrangements.

For purposes of § 411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing and is signed by the parties and specifies the premises covered by the lease.

(2) The term of the agreement is at least 1 year.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the lease are set in advance and are consistent with fair market value.

(5) The charges are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The agreement would be commercially reasonable even if no referrals